§170.315(c)(3) Clinical quality measures (CQMs) – report

2015 Edition Cures Update CCG

Version 1.0 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	06-15-2020

Regulation Text

Regulation Text

§170.315(c)(3) *Clinical quality measures—report—*

Enable a user to electronically create a data file for transmission of clinica
data in accordance with the applicable implementation specifications spe
implementation guides for Quality Reporting Document Architecture (QRD
inpatient measures in § 170.205(h)(3) and CMS implementation guide for Q
ambulatory measures in § 170.205(k)(3).

Standard(s) Referenced

Paragraph (c)(3)(i)

§ 170.205(h)(2) Health Level 7 (HL7®) CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I (QRDA I); Release 1, DSTU Release 3 (US Realm)), Volume 1

§ 170.205(k)(1) Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2

§ 170.205(k)(2) Errata to the HL7® Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014

Paragraph (c)(3)(ii)

The standards will be specified by CMS in its regulations and program guidance. For more information please reference CMS's QRDA page.

Certification Companion Guide: Clinical quality measures (CQMs) – report (Cures)

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Final Rule (ONC Cures Act Final Rule). It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the ONC Cures Act Final Rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(ACB must ensure that a product presented for certification to a § 170.315(c criterion includes the privacy and security criteria (adopted in § 170.315(d) of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need t with this specific paragraph (c) criterion unless it is the only criterion fo requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, an exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.
- § 170.315(d)(2)(i)(C) is not required if the scope of the Health IT Module does not have end-user device encryption features.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces that enable the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certificat
170.315(g)(4) and § 170.315(g)(5)) must also be certified in order for the pro

- When a single quality management system (QMS) is used, the QMS only
once. Otherwise, when different QMS are used, each QMS needs to be se
every capability to which it was applied.
- When a single accessibility-centered design standard is used, the stand
identified once. Otherwise, the accessibility-centered design standards
for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The specific version, number, and type of clinical quality measures (CQMs) presented for certification are determined at the developer's discretion. We recommend developers consult any CMS or other programs' requirements around the specific version, number, or type of CQMs required for providers in determining the CQMs presented for certification.
- Certain CMS programs require or provide the option for electronic CQM (eCQM) reporting. These programs include the EHR Incentive Program, the Physician Quality Reporting System, the Hospital Inpatient Quality Reporting Program, the Comprehensive Primary Care (CPC) initiative, CPC Plus, and the Value-Based Payment Modifier Program. Each year, CMS issues annual updates to eCQMs (herein referred to as the "CMS annual measure update(s)") which are published on the Electronic Clinical Quality Improvement (eCQI) Resource Center. The CMS annual measure updates rely upon specific versions of the HL7 Quality Reporting Document Architecture (QRDA) Category I and Category III standards. Each year's HL7 QRDA Category I and Category III standards are referenced in the corresponding CMS QRDA Implementation Guides (IGs) associated with that program year and CM update. The CMS QRDA Category I and Category III IGs also contain add form and manner requirements necessary for reporting to CMS progra necessary for the corresponding testing tools to keep pace with these n CMS reporting requirements. Thus, health IT developers are permitted t certified to the applicable CMS annual measure update and use the cor HL7 QRDA Category I and Category III standards as referenced in the CM and Category III IGs.
- After technology is certified to specific CQMs for this 2015 Edition certification criterion at § 170.315(c)(3), technology is not required to recertify to the annual measure specification updates CMS issues to maintain 2015 Edition certification unless that product is relabeled. Said another way, other programs, such as the EHR Incentive Program, may require developers upgrade their technology to the newest CQM specifications, but the technology is not required to be retested or recertified unless explicitly specified in other program requirements. [see Frequently Asked Questions #42] It is expected that all systems will test all measure and standards updates as a best practice. The testing tools are available for each CMS annual measure update and when there are late standards errata or CMS requirement changes to facilitate additional testing.
- For the purposes of automated testing to meet certification requirements, only errors (but not warnings) generated during testing would constitute a failure to meet certification

requirements.

Paragraph (c)(3)

Technical outcome – Enable a user to electronically create a data file for transmission of CQM data in accordance with the CMS QRDA Category I IG for inpatient measures as adopted in § 170.205(h)(3) and CMS QRDA Category III IG for ambulatory measures as adopted in § 170.205 (k)(3).

Clarifications:

- Developers would be able to update certified health IT to newer versions of the CMS QRDA Category I and Category III IGs through the Real World Testing Maintenance of Certification provision for standards and implementation specification updates in § 170.405(b).
- For details on the latest CMS QRDA Category I and Category III IGs, we refer readers to the eCQI Resource Center website.
- In order to prevent unintended burden by tailoring the requirements to the type of measures being tested ONC has provided the following clarifications: For the updated certification criterion "CQMs—report" in § 170.315(c)(3) a Health IT Module testing only inpatient measures would test only with the CMS QRDA Category I IG and a Health IT Module testing only ambulatory measures would test only with the CMS QRDA Category III IG. A Health IT Module supporting both inpatient and ambulatory measures would be required to test with both the CMS QRDA Category I and Category III IGs.
- The following links are references to CMS CQM reporting resources:
  - CMS and ONC eCQI Resource Center
  - CMS Quality Measure Basics
  - CMS EHR Incentive Program Resource Page (contains program requirements, reporting requirements, and other resources for each program year).

Content last reviewed on June 22, 2020